FILED
2021 Oct-12 PM 04:56
U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

EDWIN R. BANKS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 5:20-cv-0565-LCB**
	)	
ALEX AZAR,	)	**OPPOSED**
	)	
Defendant.	)	
	)	
	)	

EDWIN BANK'S MOTION FOR DISCOVERY

Pursuant to this Court's Order of September 20, 2021, Mr. Banks submits the following motion to take discovery in aid of standing. The discovery sought directly addresses the Secretary's arguments that standing is not present in this case. Further, the sought-after discovery (confidential decisions of the Secretary himself) is available only from the Secretary and from no other source. Because the discovery seeks relevant, admissible evidence and there has been no showing that it is not proportional/unduly burdensome, the discovery should be ordered. The discovery sought is pursuant to the Eleventh Circuit's remand for the purpose of completing the "record" and "consideration of supplemental evidence."

I. BACKGROUND

A. Medicare Eligibility

In order to even be eligible for Medicare, a person (or their spouse) must have paid Medicare taxes for 10 years and otherwise qualify (*e.g.*, be 65 or older). *See* 42 U.S.C. §§ 402, 414, and 1395c. Then, if the person elects, he or she can pay additional money (*i.e.*, premiums) to be covered by Medicare Part B. Medicare Part B is a voluntary insurance program financed by premiums that covers various non-hospital expenses, including durable medical equipment. *See* 42 U.S.C. §§ 1395j and 1395k.

As required by the statutes, the Secretary determines the amount of the premiums based on individual characteristics (*e.g.*, the person's adjusted gross income (AGI)), ways in which the premiums can be paid, and is required to terminate coverage for non-payment of the premiums. *See* 42 U.S.C. §§ 1395r (determining the amount of premiums); 1395s (payment of premiums); and 1395q(b)(2) (coverage terminated for non-payment of premiums).

In exchange for payment of the premiums, beneficiaries are "entitled" to have Medicare pay for qualifying services/devices. *See* 42 U.S.C. §§ 1395ff(a)(1)(A) and 1395k(a)(1)/(a)(2).[1]

[1] Absent payment of qualifying claims, there would be no point in beneficiaries paying premiums and they could keep their money.

B. Medicare Claim Process

Persons who are eligible, who have elected to enroll in Medicare Part B, and who have paid their premiums submit claims to Medicare just like private insurance. Claims that are filed with Medicare go through a five-level process. Decisions are confidential and not publicly available for the first four levels. At the fifth level, the default is confidential and not publicly available, unless decided otherwise by the Secretary.

First, claims are submitted for "initial determination."[2] Appeals of unfavorable initial determinations are submitted for "redetermination." Appeals of unfavorable redeterminations are submitted to the Qualified Independent Contractor (QIC) for "reconsideration." In addition to the basic issue of coverage, QIC decisions address financial liability if a claim is denied. *See* AR1789-94. Appeals of unfavorable reconsiderations go to an Administrative Law Judge (ALJ). In addition to the basic issue of coverage, ALJ' decisions address financial liability. Finally, at the fifth level, decisions of ALJ's are appealed to the Medicare Appeals Council (MAC), which also addresses financial liability. By default, MAC decisions are confidential and not publicly available, unless the MAC chooses otherwise.

[2] The terminology used here is that applicable to Medicare Part B. Medicare Part C has the same five levels but uses different terminology for the same steps.

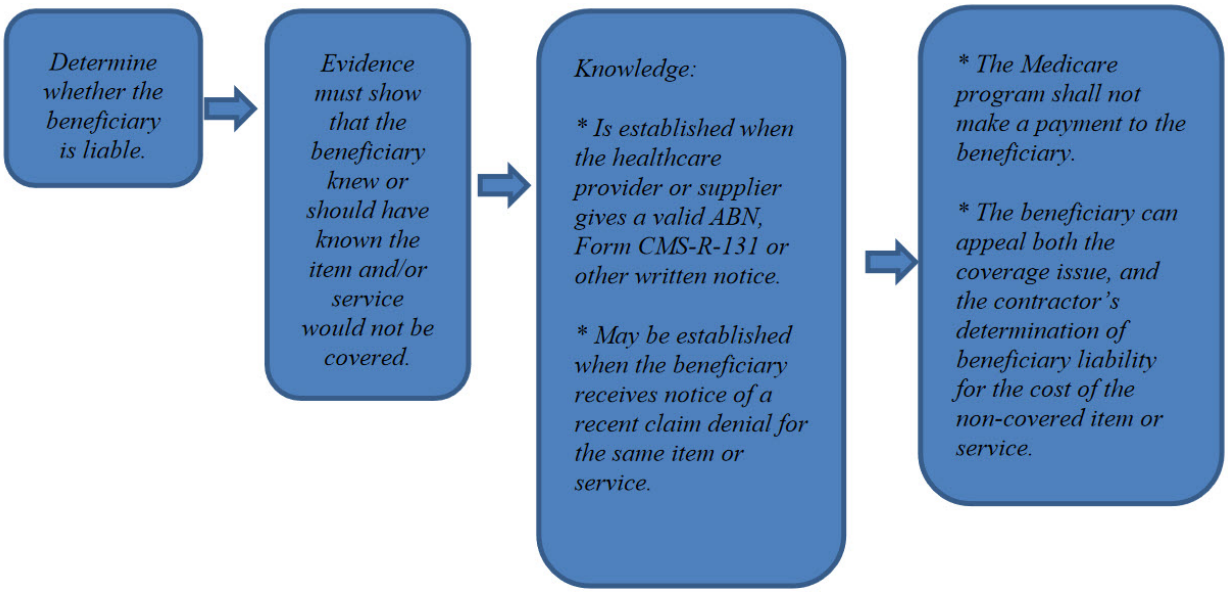
C. Medicare Payment Statutes and Regulations

Pursuant to 42 U.S.C. § 1395pp(a), even if coverage for a device/service is denied, Medicare will still pay for the device/service if neither the beneficiary nor supplier knew, or reasonably should have known, that the claim would not be paid. However, the statute provides that "thereafter" the beneficiary will be charged with such knowledge and no longer qualify under the provision. *See also* 42 C.F.R. § 411.404(b) (beneficiary deemed to have knowledge).

Once a beneficiary has knowledge that a claim has been denied, he or she will both lose the right to the "mulligan" of 42 U.S.C. § 1395pp and is exposed to personal liability under both the statute and the Secretary's own regulations and manuals regardless of an Advanced Beneficiary Notice (ABN).[3]

The Secretary's pre-litigation, claim processing manuals show that the "knowledge" of denial precluding recovery under § 1395pp can come from any source, including but not limited to an ABN. For example, MEDICARE CLAIMS PROCESSING MANUAL, Chap 30, § 30, provides:

[3] An ABN is an agreement wherein the beneficiary agrees to pay for devices/services if Medicare does not. *See* Form CMS-R-131 ("I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the [Medicare Summary Notice].").



Thus, "knowledge" may be established *either* by an ABN *or* by a "recent claim denial for the same item or service."[4] As the same page further states:

> ***NOTE:*** *If both the beneficiary and the healthcare provider or supplier are found to have knowledge, the beneficiary will be held liable.*

See also Id. at §§ 30.1 ("Knowledge based on any other means from which it is determined that the beneficiary knew, or should have known, that payment would not be made") and 30.1.1.[5]

[4] As stated, "knowledge" is established based on the "recent denial for the same item or service" and *not* the reason for the denial. Thus, the fact that claims for the same item or service were denied on different bases (*e.g.*, a different LCD) will not suffice to pull a denial outside the ambit of § 1395pp as interpreted by the Secretary.

[5] "While 42 CFR 411.404 provides criteria for beneficiary knowledge based on written notice, § 1879(a)(2) of the Act specifies only that knowledge must not exist in order to apply the [limitation of liability] provision. If it is clear and obvious that that a beneficiary in fact did know, prior to receiving an item or service, that Medicare payment for that item or service would be denied, the administrative presumption favorable to the beneficiary is rebutted. For example, if the beneficiary admits that s/he had prior knowledge that payment for an item or service would be denied, no further evidence is required. In the case in which the Medicare contractor has such evidence of prior knowledge on the beneficiary's part, the beneficiary must be held liable under the [limitation of liability] provision, even if no written notice was given by the appropriate source.").

Thus, a denial that is not reversed charges the beneficiary with "knowledge" of the denial, precludes recovery under § 1395pp, and potentially subjects the beneficiary to personal liability – as demonstrated in *Holt*, attached hereto as Exhibit A.

D. Procedural History Before this Court

Having paid his premiums (as well as at least a decade of related taxes), Mr. Banks submitted monthly claims for coverage of his brain cancer treating device (TTFT). Consistent with the standard of care, one of Mr. Bank's claims was paid as medically reasonable and necessary and a Medicare covered benefit. Another claim with the same facts was denied as not medically reasonable and necessary and not a Medicare covered benefit. In addition, the Decision contended that the sole supplier of the treatment (Novocure) - who had provided the treatment on credit – would not be paid and could not be paid.

Before this Court, the Secretary did not contest jurisdiction. After this Court dismissed this case on the grounds that collateral estoppel does not apply to Medicare cases, Mr. Banks appealed to the Eleventh Circuit.

E. Procedural History at the Eleventh Circuit

At the Eleventh Circuit, for the first time, the Secretary sought to contest standing. There, the Secretary contended that because the sole supplier of the TTFT device was deemed financially liable for Mr. Banks' treatment, Mr. Banks was not

injured by the denial of his claim. Further, the Secretary contended that Mr. Banks could never be held personally liable for his treatments unless he executed an ABN.

Mr. Banks responded on several grounds, one of which was that the denial of Mr. Banks' claim in this case would make Mr. Banks ineligible for payment of future claims under the Medicare "mulligan" provisions and that Mr. Banks could be held personally liable for his treatments even in the absence of an ABN. Mr. Banks supported his argument by seeking judicial notice of a decision (hereinafter, the "*Holt* decision") where that is exactly what happened. In *Holt*, a Medicare beneficiary suffering from GBM and seeking coverage for the same treatment was held personally liable for more than $60,000, even in the absence of an ABN, as a result of an earlier denial.

The Secretary opposed Mr. Banks request for judicial notice arguing that: 1) the *Holt* decision should not be considered because Mr. Banks did not present *Holt* before this Court (where standing was uncontested); 2) that *Holt* was irrelevant because the statutes and regulations should not be read that way; and 3) that Banks could face no personal liability without an ABN.

On July 26, 2021, the Eleventh Circuit vacated this Court's decision and remanded this matter for "additional jurisdictional factfinding and a ruling on the issue of Article III standing in the first instance." 2021 WL 3138562 at *1 (11th Cir. 2021). In particular, the Eleventh Circuit noted the factual disagreement about how

the statutes and regulations have been applied by the Secretary and held: "the parties' arguments on standing require resolving factual disputes." Id. at *3.

F. Procedural History on Remand

In order to rebut the Secretary's arguments regarding liability and the *Holt* decision, Mr. Banks notified the Secretary that he would be seeking:

> All ALJ and QIC/IRE decisions issued in the last 2 years (*i.e.*, September 1, 2019-September 1, 2021) in beneficiary appeals that were not fully favorable and were not dismissed on procedural grounds.

This request is narrowly tailored to only those materials likely to shed light on the issue and the Secretary has already identified the relevant materials at the ALJ level (comprising ~33% of the decisions).[6] Further, Mr. Banks offered that the production could be accomplished under an appropriate protective order, so that no review or designation of the materials would be needed.[7]

With these materials, Mr. Banks seeks to identify other decisions (like *Holt*) where beneficiaries were held personally liable, based on a prior denial, even in the absence of an ABN. These materials will directly address the Secretary's criticisms of the *Holt* decision. In addition, these materials will demonstrate how the Secretary was actually applying the statutes and regulations, regardless of his arguments in

[6] *See* https://www.hhs.gov/about/agencies/omha/about/current-workload/decision-statistics/index.html.

[7] In other litigation, it is reported that the Secretary produced more than 430 ALJ and MAC decisions under a protective order. *See Lewis v. Azar*, Case No. 18-cv-2929 (D.D.C.) (Walton, J.), Dkt #63 at 10.

litigation. Thus, this evidence will have a tendency to make it more likely than not that, if the denial in this case is not reversed, Mr. Banks will lose the Medicare "mulligan" and will be subject to personal liability, even in the absence of an ABN.

Alternatively, Mr. Banks proposed a stipulation to avoid the need for discovery. In particular, Mr. Banks proposed:

> The Secretary stipulates that, even in the absence of an ABN, if a claim for TTFT is denied, then the beneficiary is charged with knowledge of that denial, loses their right to payment under 42 U.S.C. § 1395pp, and may be held personally liable for future claims.

The Secretary rejected both discovery and the stipulation but did not reveal the basis for his objections.

During the status conference held on September 14, 2021, for the first time, the Secretary contended that producing the information will be unduly burdensome but, to Plaintiff's recollection, did not dispute its relevance. This briefing followed.

G. Legal Background

Pursuant to FED.R.CIV.P. 26(b)(1), parties may obtain discovery of information that is relevant to a claim or defense and proportional given a variety of factors including the parties relative access to the information. "The lack of evidence related to threatened injury should in many cases lead a court to permit discovery and to make factual findings before dismissing a suit." *See Hardwick v. Bowers*, 760 F.2d 1202, 1206 (11th Cir, 1985), *reversed on other grounds*, 476 U.S. 186

(1986). Further, "the Federal Rules of Civil Procedure strongly favor full discovery whenever possible." *See Republic of Ecuador v. Hinchee*, 741 F.3d 1185, 1189 (11th Cir. 2013) (cleaned up). As one Court in this District put it:

> The party resisting discovery has a heavy burden of showing why the requested discovery should not be permitted with the onus on the party resisting discovery to demonstrate specifically how the objected-to-information is unnecessary, unreasonable or otherwise unduly burdensome.

See Rosen v. Provident Life & Accident Ins. Co., 308 F.R.D. 670, 678 (N.D. Ala. 2015) (cleaned up).

In addition, evidence that a party has previously adopted a different position in litigation is both relevant and admissible. *See, e.g.*, *Mitchell v. Fruehauf Corp.*, 568 F.2d 1139 (5th Cir.1978) ("Prior pleadings are admissible if such pleadings indicate that the party against whom they are admitted has adopted a position inconsistent with that in the earlier litigation."). Likewise, agency interpretations developed through agency adjudication (as, *e.g.*, in the *Holt*' decision) are entitled to substantial deference, while mere "litigation positions" (as, *e.g.*, in this case) are not. *See, e.g.*, *Martin v. Occupational Safety & Health Review Comm.*, 499 U.S. 144, 156-7 (1991) ("appellate counsel's '*post-hoc* rationalizations' for agency action" not entitled to deference).

II. DISCUSSION

As an initial matter, it appears beyond reasonable dispute that *Holt* is relevant to the issue of standing because the sheer existence of *Holt* rebuts the Secretary's assertions about the role of ABNs and personal financial liability. Thus, as the Eleventh Circuit correctly summarized, unless the denial in this case is reversed, Mr. Banks will lose the Medicare "mulligan" and he will face personal liability on future claims, even in the absence of an ABN. The loss of the Medicare "mulligan" and prospect of financial liability is both a present injury and a substantial risk of future harm sufficient to confer standing. *See Banks*, 2021 WL 3138562 at *3 (*citing Jayne v. Sherman*, 706 F.3d 994, 1000 (9th Circuit)) ("that point is now or never").

As detailed above, the Secretary has disputed this position by contending that *Holt* was later reversed (though on different grounds), that Banks' position is not how the statutes and regulations should be read or applied, and that Mr. Banks faces no prospect of financial liability absent an ABN.[8] The Secretary does so, while concealing the evidence that will allow Mr. Banks to rebut these contentions (*i.e.*, that actual decisions applying the statutes and regulations). Indeed, absent the coincidence that Mr. Banks and the beneficiary at issue in *Holt* share the same

[8] Curiously, to counsel's knowledge, the Secretary has never contended that *Holt* was wrongly decided as to financial liability.

counsel, counsel would not have been aware of *Holt* to rely on - as the Secretary admitted in other proceedings.

The sought-after discovery is necessary to rebut the Secretary's contentions. The Secretary doesn't like *Holt* and claims it is a one-off? Fine. The requested discovery seeks other instances where the statutes and regulations were applied as Banks asserts. The Secretary says that *Holt* is wrong and that the statutes and regulations should not be read that way?[9] Fine. The requested discovery is designed to rebut the Secretary's contentions. Indeed, regardless of how the Secretary says that the statutes and regulations *should* be read, the requested discovery goes to the heart of the standing inquiry because it will show how the Secretary actually has been *applying* the statutes and regulations. The Secretary should not now be heard to argue that the statutes and regulations should be read and applied one way, while concealing the evidence of how he has applied the statutes and regulations in actual practice.

Given the relevance and admissibility of the requested discovery, the only issue that can remain is proportionality/burden. As noted above, that is an issue on which the onus is on the Secretary and, to date, the Secretary has made no such showing. *Rosen*, 308 F.R.D. at 678.

[9] Although in doing so, the Secretary never explains what purpose the relevant portions of the Medicare Claims Processing Manual would have under his proposed readings.

Nevertheless, as detailed above, the Secretary has already identified the relevant materials at least at the ALJ stage. Further, any production can be accomplished under a blanket protective order, so the Secretary does not even have to review the materials. Additionally, given that all of the materials are stored electronically, the burden of copying one decision is the same as copying 100, or 1,000, or 10,000. Finally, whatever burden is alleged, the standard is "unduly burdensome" and, given the importance of the issue to the case, the proportion/burden is appropriate.

Indeed, absent the requested discovery, the purpose of the Eleventh Circuit's remand would appear to be frustrated. The Eleventh Circuit had Holt before it and could have easily made the relevant determinations. Instead, the Eleventh Circuit remanded this case to develop a complete record and for consideration of "supplemental evidence as appropriate."

All of this could be avoided if the Secretary agreed to the proposed stipulation (which summarizes *Holt* with regard to financial liability). Given the Secretary's refusal to do so, the discovery is needed to address the factual dispute as to whether Mr. Banks will lose the Medicare "mulligan" and face personal liability on future claims unless the decision in this case is reversed.

III. CONCLUSION

For the reasons set forth above, the requested discovery should be ordered.

/s/Robert R. Baugh
Robert R. Baugh
Attorney for Plaintiff

OF COUNSEL:
DENTONS SIROTE PC
2311 Highland Avenue South
Post Office Box 55727
Birmingham, AL 35255-5727
Tel: 205-930-5307
robert.baugh@dentons.com

-AND-

PARRISH LAW OFFICES
James C. Pistorino
788 Washington Road
Pittsburgh, PA 15228
Telephone: (412) 561-6250
james@dparrishlaw.com

CERTIFICATE OF SERVICE

I hereby certify that on October 12, 2021 I filed the foregoing with the Clerk of Court using the CM/ECF electronic filing system which will send notification of such filing to all counsel of record in this case.

/s/Robert R. Baugh
OF COUNSEL